IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8427

Bartle, C.J. March 12, 2010

Jacqueline M. Hunecke ("Ms. Hunecke" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Stephen Raskin, M.D., F.A.C.C. Based on an echocardiogram dated December 30, 2002, Dr. Raskin attested in Part II of Ms. Hunecke's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and

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2. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

arrhythmias.[3] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $462,103.[4]

In the report of claimant's echocardiogram, the reviewing cardiologist, Helbert V. Acosta, M.D., stated that claimant had "[m]oderate [mitral regurgitation]," which he measured at 35%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2005, the Trust forwarded the claim for review by Siu-Sun Yao, M.D., F.A.C.C., one of its auditing cardiologists.[5] In audit, Dr. Yao concluded that there was no

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3. Dr. Raskin also attested that claimant suffered from mild aortic regurgitation and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the presence of an abnormal left atrial dimension and arrhythmias, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. It appears that Dr. Yao's statement in the Certification of Auditing Cardiologist that he reviewed Ms. Hunecke's claim on or about August 28, 2005 is incorrect. According to the Transmittal to Auditing Cardiologist and the Trust's statement of the case, the Trust transmitted Ms. Hunecke's file to Dr. Yao in October, 2005. In addition, Dr. Yao stated in the Attestation of Auditing Cardiologist that he completed his audit of

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reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Yao explained that the "[t]echnical settings [are] improper. Nyquist limit 41 cm/sec (later on echo tape Nyquist limit 51 cm/sec). Color gain appearance too high. Both these factors falsely increase appearance of [mitral regurgitation]." Dr. Yao further noted that the "sonographer incorrectly traced [mitral regurgitation]-RJA, including tracing of non-regurgitant flow."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Hunecke's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted a report from Dr. Raskin, who declared, in pertinent part, that:

> My review of the study finds that the December 30, 2002 echocardiogram reveals a central [mitral regurgitant] jet. While Dr. Yao is correct that [mitral

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5. (...continued)
Ms. Hunecke's claim on October 17, 2005.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Hunecke's claim.

> regurgitation] severity may be manipulated by lower than recommended Nyquist settings, in this case an appropriate Nyquist setting exceeding 50 cm/s is utilized correctly for the determination of [mitral regurgitation] severity. The minimal Nyquist requirement of 50-60cm/s as defined by the American Society of Echocardiography 2003 recommendations for the evaluation of native valvular regurgitation are met in the Hunecke study. Dr. Yao's generic concern about Nyquist limits is thus not relevant to this case.

In addition, Dr. Raskin retraced the mitral regurgitant jet boundary "to avoid including black (no color) areas" of the left atrium or any areas of non-regurgitant flow. Based on two still frames that were attached to his declaration, Dr. Raskin opined that:

> Dr. Yao correctly notes that overestimation of the [mitral regurgitant] jet is present in the Hunecke study .... While one of the jets ... is more representative of the correct [mitral regurgitant] jet, it too does over-represent the severity of [mitral regurgitation]. In this case, my own read of the [mitral regurgitant] jet boundary was traced with care to avoid including black (no color) areas of the [left atrium] or any entrained or non-regurgitant flow. While my corrected estimate of jet area is smaller (6 cm^2) than the [RJA] shown on the tracings at 9.5 cm^2, the calculated RJA/LAA remains greater than 20% and remains consistent with the AHP Trust definition for moderate [mitral regurgitation].

Claimant contended that Dr. Raskin's report provided a reasonable medical basis for her claim.

Although not required to do so, the Trust submitted the claim to the auditing cardiologist for a second review. Dr. Yao submitted a declaration in which he again concluded that there

was no reasonable medical basis for Dr. Raskin's finding of moderate mitral regurgitation. Specifically, Dr. Yao stated:

> I again observed that the December 30, 2002 echocardiogram depicted mild mitral regurgitation in real time.
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> Improper settings in Claimant's echocardiogram study served to exaggerate the apparent level of mitral regurgitation. Excessive color gain and low Nyquist limits (at 41 cm/sec and 51 cm/sec) were used throughout the study, exaggerating Claimant's apparent [RJA]. In addition, the RJA was overtraced to include non-regurgitant flow.
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> When the planimetry of the RJA on Claimant's echocardiogram is corrected to eliminate the non-regurgitant flow from the measurement, and the settings on Claimant's study are taken into account, I find that Claimant's RJA/LAA ratio is less than 20%.
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> Based on my review, Claimant does have mitral regurgitation, but her RJA/LAA ratio never reaches 20%.

The Trust then issued a final post-audit determination, again denying Ms. Hunecke's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Hunecke's claim should be paid. On July 6, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6410 (July 6, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting

documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 27, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[7] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Hunecke reiterates the arguments that she made in contest. Specifically, claimant notes that Dr. Yao's arguments regarding the Nyquist limit settings are misleading because an acceptable Nyquist limit of 51 cm/sec was used in the echocardiogram when the RJA/LAA ratio was measured. Ms. Hunecke asserts that the Trust fails to explain why an otherwise acceptable Nyquist limit setting would be improper here. Claimant further suggests that the sonographer's improper tracing of the RJA is not dispositive because, when retraced to exclude non-regurgitant flow, the accurate RJA/LAA ratio exceeds 20%, consistent with moderate mitral regurgitation, as demonstrated by Dr. Raskin's RJA/LAA ratio measurement of 26.7% in the color image attached to his declaration. Finally, claimant submits that her echocardiogram does not contain evidence of excessive color gain, including increased color pixilation in non-moving anatomic regions.

In response, the Trust argues that Dr. Raskin's declaration fails to provide a reasonable medical basis for his finding of moderate mitral regurgitation. According to the Trust, Dr. Raskin's opinion is beyond the bounds of medical reason because it is based on an echocardiogram that has: (1) over-manipulated settings; (2) a low Nyquist limit; (3) backflow characterized as regurgitation; and (4) an

overtraced amount of regurgitation. In addition, the Trust notes that although Dr. Raskin acknowledges the mitral regurgitant jet is overestimated, he insists that the RJA/LAA ratio is greater than 20%.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson determined that:

> In reviewing the transthoracic echocardiogram from 12/30/02, my visual estimate is that there is moderate mitral regurgitation. Regarding the Nyquist limit, it is at 41 cm/sec in one image, then 46 cm/sec for two images. For the remainder of the images, the Nyquist limit is at 51 cm/sec, which is slightly lower than normal and will increase the appearance of the mitral regurgitation more than a Nyquist limit set at 60 to 70 cm/sec. The color gains are slightly increased throughout this study. Despite these two settings that will increase the apparent jet size, I believe this Claimant would have moderate mitral regurgitation even if the usual settings were used. I also agree that the regurgitant jet areas on the tape are over traced. Therefore, I re-measured these two jets. My measurements for these two jet areas/left atrial areas are 8.8 cm2/30.8 cm2 and 6.6 cm2/24.6 cm2. I also measured three other RJA/LAA ratios. These measurements are 8.1 cm2/28.8 cm2, 8.3 cm2/26.9 cm2, and 8.8 cm2/25.6 cm2. These ratios are 29%, 27%, 28%, 31%, and 34%, all of which are greater than 20%, and are consistent with moderate mitral regurgitation.
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> In summary, there is a reasonable medical basis for the Attesting Physician's claim that this Claimant has moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician, Dr. Raskin, reviewed claimant's echocardiogram twice and found that claimant had moderate mitral regurgitation. Although the Trust challenged the attesting physician's finding, Dr. Abramson confirmed Dr. Raskin's finding of moderate mitral regurgitation.[8] Specifically, Dr. Abramson measured claimant's regurgitant jets and concluded that the "ratios are 29%, 27%, 28%, 31%, and 34%, all of which are greater than 20%, and are consistent with moderate mitral regurgitation."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Abramson found that claimant's RJA/LAA ratio was greater than 20%. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Hunecke for Matrix Benefits.

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8. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.